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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,286	11/14/2001	Donald M. McDonald	UCSF-077CON2	6344

7590

07/25/2003

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/25/2003

Y

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/004,286

Applicant(s)

McDonald

Examiner

Gollamudi Kishore

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 13, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21, 24-28, and 31-35 is/are pending in the application.
- 4a) Of the above, claim(s) 31-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21, 24-28, and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

**The request for the extension of time and amendment filed on 5-13-03 are acknowledged.**

**Newly submitted claims 31-34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally presented claims were directed to cationic liposomes, whereas said claims 31-34 are directed to a method of selectively labeling angiogenic endothelial cells.**

**Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31-34 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.**

**Claims included in the prosecution are 21, 24-28 and 35.**

### ***Claim Rejections - 35 U.S.C. § 102***

**1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless --**

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 21, 24-29 and 35 are rejected under 35 U.S.C. 102(a) as being anticipated by Wasan (Journal of Pharmaceutical Sciences, 85, # 4, April 1996).

Wasan discloses cationic liposomes containing a detectable label. The liposomes have sizes of 125-150 nm (note the experimental section on col. 1, page 428).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 21, 24-29 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Felgner (PNAS, 1987).

Felgner discloses Fluorescent labeled cationic lipid-DNA complexes (note col. 1 on page 7414).

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 21, 24-29 are rejected under 35 U.S.C. 102(e) as being anticipated by DePrince (5,705,693).

DePrince discloses Fluorescent labeled cationic lipid-nucleic acid complexes (columns 27-28).

Applicant's arguments to the above rejections have been fully considered, but are not found to be persuasive. Applicant argues that the references do not teach the zeta

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potentials ( a measure of charge and the electrophoretic mobility. This argument is not found to be persuasive since the references and instant invention use the same cationic lipids, the zeta potentials of greater than 0 mv are inherent in the prior art liposomes. In addition, the examiner points out that instant specification on page 17, lines 7-8 states that any cationic lipid could be used and there is no specific showing of how the zeta potentials are measured. With regard to the limitation of 'greater affinity for angiogenic endothelial cells', instant claims are composition claims and applicant has not established that the prior art liposomes do not possess that ability.

*Claim Rejections - 35 U.S.C. § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 21, 24-29 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Folkman (5,837,682) in view of Felgner (PNAS) or DePrince (5,705,693) cited above or vice versa (Felgner or DePrince in view of Folkman).

Folkman discloses lipofectin-DNA complexes; the DNA sequence encodes angiostatin. The complex however does not contain a detectable label (abstract, column 39, line 4 et seq.).

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**Felgner and DePrince as pointed out above disclose Fluorescent labeled cationic lipid-DNA complexes . The fluorescent labeling is for the purpose of identification of the cells which were transfected. Therefore, one of ordinary skill in the art would be motivated to label the complexes of Folkman if the purpose is also to identify the cell populations transfected.**

**Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again center around the lack of teachings in prior art of the compositions having greater affinity for angiogenic endothelial cells as compared to normal endothelial cells and the lack of teachings of zeta potentials. These have been addressed above. Applicant's arguments that none of the references disclose cationic liposomes for in vivo use, the examiner points out that instant claims are composition claims and not method claims and do not recite any specific components. Furthermore, the references are suggestive of the applicability in vivo (see 'Applications' on columns 19-20 of DePrince for example).**

**The references of Papahadjopoulos (6,426,086) and Pillai (6,271,206) which discuss zeta potentials are cited of interest (col. 20, line 63 et seq., of 086; col. 12, line 18 et seq., of 206) are cited of interest.**

**7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

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**A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.**

**8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

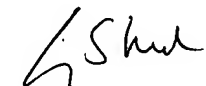
**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**



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**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**July 23, 2003**